

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS**

In Re: PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION)	MDL No. 1456
)	
)	Master File No. 01-CV-12257
)	Subcategory Case. No. 06-11337
)	
THIS DOCUMENT RELATES TO:)	Hon. Patti B. Saris
<i>U.S. ex rel. Ven-A-Care of the Florida Keys, Inc. v. Dey, Inc., et al.</i>)	
)	
Civil Action No. 05-11084-PBS)	
)	

**DEFENDANTS DEY, INC., DEY, L.P., AND DEY L.P., INC.'S
REPLY IN FURTHER SUPPORT OF MOTION TO COMPEL
PRODUCTION OF DOCUMENTS RESPONSIVE TO SUBPOENA**

Defendants Dey, Inc., Dey, L.P., and Dey L.P., Inc. (collectively, "Dey"), through their undersigned counsel, respectfully submit this reply memorandum in further support of their motion to compel production of documents responsive to subpoenas served on four state Medicaid agencies in Delaware, North Carolina, Oklahoma, and South Dakota.

The Delaware Department of Health and Human Services ("Delaware"), the North Carolina Department of Health and Human Services ("North Carolina"), the Oklahoma Health Care Authority ("Oklahoma"), and the South Dakota Department of Social Services ("South Dakota") have individually filed or served responses or other documents addressing Dey's motion to compel in various courts.¹ Given Dey's willingness to pay for reasonable costs

¹ Delaware filed its opposition to Dey's Motion to Compel in this Court on January 5, 2009 as an attachment to a *pro hac vice* application, and submitted the hard copy of the motion for filing on January 7, 2009. See Dkt. 141-3 and 5845. North Carolina filed its Memorandum in Opposition to Dey Defendants' Motion to Compel Production of Documents in the United States District Court for the Eastern District of North Carolina on December 31, 2008 and a courtesy copy was provided with this Court. See Ex. A to Reid Decl. South Dakota filed a "Memorandum and Opposition to Defendant Dey's Motion to Compel Production of Documents Responsive to Subpoena" on December 30, 2008 in the United States District Court of the District of South Dakota and a courtesy copy was provided to this Court. See Ex. B to Reid Decl. Oklahoma served its Objection

and Dey's pending Motion to Extend the Production Deadline for the Limited Purpose of Receiving Medicaid Claims Data from the States ("Motion to Extend") (Dkt. 5765), the oppositions filed by the individual state Medicaid agencies do not demonstrate any undue burden which would prevent them from providing Dey claims data necessary to its defenses.

In addition to the individual responses, after the deadline for opposition to Dey's motion to compel, December 29, 2008, had passed, Plaintiff the United States submitted its own memorandum in opposition to Dey's Motion to Compel Production of Documents Responsive to Subpoena. (Dkt. 5508). The United States does not have standing to oppose Dey's motion to compel the four states to produce claims data pursuant to subpoenas that were timely served on those state Medicaid agencies. Even if the United States did have standing to oppose Dey's motion, they present no reason why this Court should not compel the claims data necessary to Dey's defenses. Therefore, this Court should grant Dey's motion to compel Delaware, North Carolina, Oklahoma, and South Dakota to produce the claims data sought in the subpoenas.

I. THE CLAIMS DATA SOUGHT BY DEY IS NECESSARY TO DEY'S DEFENSES

The claims data sought in the subpoenas to Delaware, North Carolina, South Dakota, and Oklahoma is necessary to determine which claims, if any, were paid using Dey's AWP's and WACs. The state claims data which Dey subpoenaed is also needed to rebut Plaintiffs' expert opinion. Dey requires state claims data in order to demonstrate that Plaintiffs' approach to damages and reliance on the CMS data that is publicly available is fundamentally flawed because this data does not show the basis of payment for all states and all time periods. The state claims data sought by Dey is needed to determine how claims were actually paid – a

to Dey Defendants' Motion on December 29, 2008. *See* Ex. C to Reid Decl. There is no indication as to whether Oklahoma filed its objection with this Court, and a search in this Court's docket did not show such a filing. None of these four documents were timely filed by the deadline for oppositions to Dey's motion, December 29, 2008.

calculation that can only be performed accurately using state claims data. The reimbursement basis is crucial to Dey's damages analysis. Since Plaintiff has alleged only that it has suffered damages as a result of AWP's and WAC's reported by Dey, at a minimum Dey cannot be liable for any claims not reimbursed on the basis of Dey's reported AWP's or WAC's. *See State of California v. Abbott Labs., Inc.*, No. 03-CV-2238, Memorandum and Order dated 3/22/07 at 30-32. The claims data sought from these four states is also necessary to determine if there are discrepancies between a state's reimbursement policies and that state's actual reimbursement practices which is an issue in several states. These issues directly impact both liability and any damages analysis. Moreover, Dey should not be held liable for any claims not reimbursed on the basis of Dey's AWP or WAC.²

II. THE INDIVIDUAL STATE MEDICAID AGENCIES HAVE NOT DEMONSTRATED WHY THEY SHOULD BE EXCUSED FROM PROVIDING THE CLAIMS DATA NECESSARY TO DEY'S DEFENSES

In the oppositions or other responses from Delaware, North Carolina, South Dakota, and Oklahoma, the state Medicaid agencies proffer two basic reasons why they should not have to comply with Dey's subpoenas seeking claims data. First, that the states argue that they were not given enough time to comply with the subpoena, and second, the states claim that the subpoenas are unduly burdensome. With respect to the timing issue, Dey has filed a motion to extend the discovery deadline which is pending before this Court and which would allow for additional time for the four state agencies to respond, which would alleviate this concern. *See* Dkt. 5765.

The state Medicaid agencies object to the burden of producing data going back to 1991. However, the time frame of this lawsuit was determined by Plaintiffs, and not Dey.

² Dey incorporates by reference its Reply to the Motion to Extend, Dkt. 5822.

Because Plaintiffs are seeking damages for the federal share of these states' Medicaid payments from "on or before December 31, 1992 . . . to the present," Dey must evaluate the actual claims paid for Dey's drugs during that period. See Docket 5164, United States First Amended Complaint at ¶ 50. The states should not be permitted to avoid compliance with Dey's subpoenas because of the length of time covered by Plaintiffs' complaint. The states' other claims of burden are addressed individually below.

A. Delaware

Delaware filed its opposition to Dey's Motion to Compel in this Court on January 5, 2009 as an attachment to a *pro hac vice* application, and submitted the motion for filing on January 7, 2009. See Dkts. 141-3, and 5845.³ Delaware admits that the information sought by Dey exists, but states that it would be an undue burden to extract that information. At this time, Delaware states that it cannot provide exact costs of the project but that it would take approximately six months to a year and \$500,000 to \$1,000,000 to produce the data requested. It appears that this very high estimate is based, in part, on the costs to purchase the necessary hardware and software to process the claims data so that it can be produced in a readable format. Clearly, that is an unreasonable time frame and cost, and indeed other much larger states have produced claims data to Plaintiffs and/or Dey at little or no cost. It appears that one solution lies in requesting another state for use of its necessary hardware and software. The O'Connor affidavit submitted with Delaware's response states that "[i]f another state Medicaid program

³ On December 4, 2008, prior to the filing of Dey's Motion to Compel, Delaware filed a Motion to Quash Dey's subpoena in the District Court for the District of Delaware, thus making it apparent that it would not be providing the claims data and other information requested by Dey. See Ex. F to Reid Decl. Dey has opposed this motion and filed a cross-motion to transfer to this Court. See Ex. G to Reid Decl. Delaware submitted its reply in the District of Delaware as did Dey. See Exs. H and I to Reid Decl. Dey incorporates its arguments in opposition to the motion to quash and in support of a transfer by reference.

would be cooperative, it is likely that portion of the cost would be less than if Delaware had to purchase or lease the hardware and software.” (O’Connor Dec. at ¶3). It is not an undue burden for Delaware to inquire if it may use the necessary hardware and software that is available from other states to process the requested claims data. It is likely that this will reduce both the time and costs of complying with Dey’s subpoena. The other alternative is for the Plaintiffs to withdraw their claim for damages as to Delaware as they have in Ohio. Therefore, this Court should compel Delaware to comply with Dey’s subpoena or dismiss Plaintiffs’ federal share of Medicaid claims as to Delaware.

B. North Carolina

North Carolina filed its Memorandum in Opposition to Dey Defendants’ Motion to Compel Production of Documents in the United States District Court for the Eastern District of North Carolina on December 31, 2008 and a courtesy copy was provided with this Court.⁴ North Carolina states that it could take up to six months to obtain the information sought, if it exists. *See* Ex. A to Reid Decl. at 9. While North Carolina cannot produce what it does not have, to the extent that North Carolina has claims data and MAC information relevant to Dey’s defenses, the information should be produced to Dey.

North Carolina argues that if the claims data and MAC information is relevant, “Defendants should have pursued them through formal discovery with the Plaintiff.” *See* Ex. A to Reid Decl. at 10. Dey did request this information from Plaintiffs on January 17, 2008, when Dey served document requests upon Plaintiff demanding, *inter alia*, production of “[c]omplete claims data . . . for every . . . Medicaid transaction for which the Plaintiffs seek recovery.”

Plaintiffs have represented that they requested claims data from all 50 states and has produced

⁴ North Carolina makes numerous arguments to the North Carolina Federal Court regarding jurisdiction which Dey has addressed in its response, filed on January 12, 2009 and attached as Ex. D to the Reid Decl.

claims data from 17 states. It is only because some states apparently did not respond to Plaintiffs' requests that Dey was forced to subpoena them directly. As previously stated in Dey's motion for an extension of time to obtain claims data (Dkt. 5765) and at the November 13, 2008 hearing before this court, Dey requested the exact same claims data from Plaintiffs and Plaintiffs have not produced it.

C. Oklahoma

Oklahoma served an objection on December 29, 2008, but does not appear to have filed any opposition with this Court. Oklahoma's objection to producing the requested claims data is that "it would take OHCA weeks if not months to compile such information" and that "many of these records possibly are not on database . . . and would be on microfilm" which would require someone viewing the microfilm to compile the information. *See* Ex. C to the Reid Decl. at 2. However, Oklahoma has not submitted an affidavit or any other documentation in support of its claims of burden and the vague estimate provided is not sufficient establish that it need not produce claims data necessary to Dey's defenses. Furthermore, Oklahoma contends that it complied with a subpoena seeking documents and a 30(b)(6) deposition. Oklahoma's compliance with previous requests has no bearing on the issue of the subpoena requesting claims data, which is a separate subpoena and which seeks information necessary to Dey's defenses. Therefore, Oklahoma should be compelled to produce the requested claims data and MAC information, or alternatively Plaintiffs should not be allowed to seek damages for this time period.

D. South Dakota

South Dakota filed a "Memorandum and Opposition to Defendant Dey's Motion to Compel Production of Documents Responsive to Subpoena" on December 30, 2008 in the United States District Court of the District of South Dakota and a courtesy copy was provided to

this Court. Dey filed its response to South Dakota's Opposition in the District Court for the District of South Dakota on January 9, 2009, addressing South Dakota's jurisdictional arguments, and a copy is attached as Exhibit E to the Reid Decl.

In opposition to Dey's motion to compel, South Dakota states that it will cost approximately \$960.00 to provide the historical MAC data requested and \$960.00 to provide most of the requested claims data fields for the period from 1991-1996 and 2003 to the present from a rebate database which is already in existence. *See* Ex. B to the Reid Decl. at 8, Chitwood Aff. at 5-10. South Dakota estimates that it would take approximately two weeks to compile this data. Dey is willing to pay for reasonable costs associated with the compilation of this MAC and claims data information and as evidenced by South Dakota's own submission, the compilation of this information will not result in an undue burden on the state, as the information is readily available and can be compiled with approximately 40 hours of labor. Therefore, South Dakota should be compelled to produce this information. South Dakota estimates that to provide claims data from 1997 to 2003, which is not contained in the rebate database, it will take approximately seven to eight months and \$19,200. *See* Ex. B to the Reid Decl. at 8, Chitwood Aff. at 7. Once again, because of the necessity of the claims data, South Dakota should be required to provide this information or alternatively, Plaintiffs should not be allowed to seek damages from South Dakota for this time period.

III. THE UNITED STATES DOES NOT HAVE STANDING TO OPPOSE DEY'S MOTION, AND EVEN IF THE UNITED STATES DID HAVE STANDING TO OPPOSE DEY'S MOTION, THEY HAVE NOT DEMONSTRATED WHY DEY'S MOTION SHOULD NOT BE GRANTED

Dey's motion to compel is directed to four states that have refused to produce electronic claims data in response to Dey's subpoena. In addition to the individual oppositions made by the states, the United States has submitted an opposition on behalf of all four states.

However, the United States does not have standing to oppose the motion which is not directed at the United States, but rather which seeks to enforce a subpoena for claims data served on state Medicaid agencies. *See, e.g., Donahoo v. Ohio Dep't of Youth Servs.*, 211 F.R.D. 303, 306 (N.D. Ohio 2002); *J.B. Hunt Transp., Inc. v. Adams*, 2007 U.S. Dist. LEXIS 17577 (E.D. Mich. Mar. 14, 2007).

Even if the United States did have standing to oppose Dey's motion, the reasons given in opposition of Dey's motion do not support the denial of Dey's Motion to compel. The United States argues that the motion does not leave the United States' expert time to review any additional claims data. Since it was the United States which created the delay by failing to produce claims data for these states despite Dey's request, they cannot use their delay as a way of defeating Dey's right to this critical data. In addition, as explained in Dey's Reply to its Motion to Extend, Dkt. 5822, Expert discovery is not scheduled to close until May 22, 2009. Allowing states to produce claims data does not require an extension of any other deadline.

The United States also claims that the data that has been produced is sufficient. This statement contradicts their argument that their expert would not have time to review the claims data. The data publicly available from CMS includes two categories of data, SDUD data and MAX/SMRF data. SDUD data is inadequate because it does not show whether Dey's AWP or WAC were actually used to pay claims; the data subpoenaed from the states will show this. Though MAX/SMRF data has some claims level data, it is not available for all states prior to 1999, and does not include the quantity field for any state prior to 1996. MAX/SMRF also does not include dispensing fee and co-payments, which reduces the precision of attempts to calculate the reimbursement basis. MAX/SMRF data is also rounded, which further reduces the precision of payment basis analysis. Due to these deficiencies, it is not possible to determine

how claims were actually paid – a calculation that can only be performed using state claims data.

See also Dkt. 5822.

CONCLUSION

For the above reasons, Dey respectfully requests that this Court grant its motion to compel the requested claims data and MAC information.

Dated: January 16, 2009

Respectfully Submitted,

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CERTIFICATE OF SERVICE

I certify that a true and correct copy of the foregoing was delivered to all counsel of record by electronic service pursuant to Paragraph 11 of Case Management Order No. 2, by sending on January 16, 2009 a copy to LexisNexis File and Serve for posting and notification to all parties. I further certify that on January 16, 2009, the foregoing was served by overnight mail, addressed to the following:

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